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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,431	12/03/2003	Knut Brabrand	09032.0001	5321

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
JAWORSKI, FRANCIS J	

ART UNIT	PAPER NUMBER
3737	

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/725,431	BRABRAND, KNUT	
	Examiner	Art Unit	
	Jaworski Francis J.	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/03,3,7/04 (IDSs)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14, 17 - 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 14, 17 - 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *5-3-04 (Fig. 1 legend poor))* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/3,3/29,7/19/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 – 3, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Riederer et al (US5363844, of record with the IDS of 7/19/04).

Riederer is directed to a method of determining the degree of lung inflation by non-invasively determining the position of the diaphragm with the MRI imaging system itself serving as a diaphragm position sensing device by using the MRI imaging display to display a truncated or navigational pulse scan along a line which transects the diaphragm at a location of its dome which is suitable to be reliably representative of the degree of inflation. During a reference point establishment phase the operator selects a 20 sample wide range over which signal edge extraction is practiced to track diaphragm location which is fed back to the patient by a corresponding 20 LED bar display so that the patient can breath-hold at the optimum diaphragm position with the MRI diagnostic mode image then taken after a short stabilizing delay. Therefore claims 1 – 3 are

directly met (with note that "inspiration" in line 1 may be interpreted in two variants – either read therefore 'filling' /'inflation' or read for the word 'filling during an inspiratory phase' whereupon although in fig. 3 the patient's diaphragm is shown moving upwards during exhalation to a hold position, col. 6 lines 47 – 51 in supplement is essentially saying that the patient is in actuality visually servoing to the target diaphragm location in small final increments of inspiration/exhalation).

Claims 1, 4/1, 5-8, 14 and 20 are rejected under 35 USC102(e) as anticipated by Prince (US6937883) which teaches a method and structure for non-invasive determination of a patient's diaphragm position using a one-dimensional phased array longitudinally placed over the liver and adjacent diaphragm to detect diaphragm position, the sinus being adjacent to the diaphragm and therefore being overlaid during its motion, the position of the diaphragm being determined from the beamformed aiming of the array's elements with Doppler processing for tracking of diaphragm motion during locating setup, see col. 10 lines 50 – 67.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4/(1 or 2 or 3) – 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riederer et al as argued against claims 2 or 3 above, further in view of Prince (US6937883, eff. Date 03/08/200).

Whereas Riederer et al is confined to methodology using the MRI imager itself as a sensing device for patient diaphragm position and is silent as to a primary ultrasound position sensing alternative, it would have been obvious in view of Prince to alternatively use a one-dimensional ultrasound phased array of transducer elements (cols. 2 – 3 bridging) to detect motion of the diaphragm (col. 3 lines 53 – 54) by positioning the array in a longitudinal orientation in the vicinity of the lung sinus (since the sinus or space adjacent the pleura is present about the diaphragm) and determining diaphragm position e.g. by A-scanline (single line) ensonation with Doppler motion detection within a range gate (col. 9 lines 25 – 32, col. 10 lines 58 – 67), the individual elements cooperating in the focal aiming of the array, the array itself contributing to its own aiming since the diaphragm provides large amplitude Doppler deflection once initially located, for the motivation that Prince like the former is directed to obtainance of a diagnostic MRI image using the MRI initially in a tracking-reference function, see col. 10 lines 50 – 54.

Claims 2 – 3 and 4/(2 – 3) are rejected under 35 U.S.C. 103(a) as being unpatentable over Prince as applied to claim 1 above, and further in view of Rieder et al. As noted supra, Riederer et al teaches a calibration-breath-holding technique where the patient first assists in determining a diaphragm-stationary reference point for which the MR image is optimal and thereafter the diaphragm position is returned by

breathholding to the stationary reference optimum while diagnostic imaging proceeds. It would have been obvious to supplement Prince with this capability since the Doppler tracking of the diaphragm within the range gate with triggering on the wave curve characteristics is an alternative equivalent to the time-variant LED display of the former within the 20 element range limits.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Prince as applied to claims 7 or 8 above, and further in view of Riederer et al and Amazeen et al (US4431007). Whereas the former does not speak directly to impedance change in the Z-direction with respect to diaphragm movement, Amazeen et al evidences that echoes such as returning from the patient diaphragm in Prince represent density discontinuities due to impedance changes at such interfaces. Further, since Riederer et al performs the navigational referencing using a longitudinal z-gradient field scanline through the diaphragm (see col. 5 end-portion) the Prince col.6 end-potion discussion may be understood to advise to measure z-direction movement as nearly as possible, since Doppler resolution is greatest along the direction of motion which in the case of the diaphragm is longitudinal along the patient axis.

Claims 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Riederer et al or Prince as applied respectively to claims 1, 7 above, and further in view of Wessels et al (US6314312). Whereas the former while directed to MRI diagnosis at an optimal diaphragm position do not discuss biopsy as an associated procedure, it would have been obvious in view of Wessels et al col. 1 lines 12 – 42 and col. 6 lines 22 – 62 to track organ motion in association with biopsy in order that a small lesion such as

P within the liver may be accurately targeted using the ultrasound as part of the tracking where ultrasound is used such as in Prince.

Claims 11 – 12, 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prince as applied to claim 7 above, and further in view of Hernandez-Guerra et al (EP 0 940 158 A1, of record with the 7/19/04 IDS). Whereas the former is silent as to the use of an ultrasound-array-based non-invasive diaphragm position and motion tracking system for radiation therapy, it would have been obvious in view of Hernandez-Guerra et al to utilize such a device for triggering radiotherapy in association with target movement for the reason provided in the latter, namely that a non-invasive diaphragm tracking subsystem (the SEFE redundant parameter system described in paras [0049] – [0053]) allows for long treatment times not feasible by breath-holding alone, Prince also being not relegated to a breath-holding application.

Claims1, 12-13 is also rejected under 35 U.S.C. 103(a) as being unpatentable over Hernandez-Guerra et al further in view of Riederer et al or Prince, since the former meets the claimed limitations (in the case of claim 13 since CPU 18 controls the radiotherapy source head positions) save that diaphragm position is not used as the non-invasive respiratory motion parameter however since the document states in para 53 that diaphragm movement is being tracked then the latter merely provide practicalization thereto, albeit without 4-parameter redundancy which the SEFE algorithm provides.

Mostafavi (US6937696) is cited as of interest in showing fluoroscopic tracking of the diaphragm for radiation therapy triggering, see col. 23 lines 1 – 18.

Feinberg et al (International Published Application WO-02/41776, of record) like Prince is directed to whole-image tracking of displacement (inter alia by regional displacement measurement across successive frames) using a longitudinally positioned ultrasound array, see Fig. 10.

Sontag et al (US6298260) like Hernandez-Guerra uses SEFE-based respiratory triggering.

Schweikard et al detects respiratory motion during treatment regimens.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

Francis J. Jaworski
Primary Examiner

FJJ:fjj

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